K113039

OCT 5 2012

Smith & Nephew, Inc.
510K Summary of Safety and Effectiveness
Radiopaque Trial Necks

Contact Person and Address
Natalie P. Williams
Sr. Regulatory Affairs Specialist
Smith & Nephew, Inc.
7135 Goodlett Farms Parkway
Cordova, TN 38016
(901) 399-5161

Date of Summary: 05/29/2012

Name of Device: Radiopaque Trial Necks
Common Name: Surgical Instrumentation
Device Classification Name and Reference: 21 CFR 888.3353 - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis; 21 CFR 888.3358 - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Device Class: II
Panel Code: Orthopaedics/87 LPH, MEH
Predicate Devices: SMF Hip Stem System (K080625), MDF Revision Hip System (K081124), Promos Reverse Shoulder System Trial Inserts (K081016)

Device Description
Subject of this Traditional 510(k) are the Smith & Nephew Radiopaque Trial Necks. The Radiopaque Trial Necks are intended to be used to determine the correct modular neck implant option for the femoral stems developed as part of the Smith & Nephew SMF Hip Stem System and MDF Revision Hip System cleared via premarket notifications K080625 and K081124, respectively.

The subject devices are manufactured from polyphenylsulfone (PPSU) with 6% of the radiopacifier barium sulfate, which makes them visible on an x-ray in the instance that they become dislodged during the trialing process. Colorants are blended with the PPSU resin to differentiate the various radiopaque trial necks. The subject devices are available in the options provided in Table 1 below.

Table 1: Radiopaque Trial Neck Options

Component Description	Color
Radiopaque Trial Neck Standard Offset	Natural
Radiopaque Trial Neck High Offset	Natural
Radiopaque Trial Neck Left Anteverted	Green
Radiopaque Trial Neck Right Anteverted	Red
Radiopaque Trial Neck High Offset +10MM	Natural

Intended Use
Total hip components are indicated for uncemented use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; nonunion, femoral neck

fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Performance Data

Biocompatibility testing has been conducted on the subject devices according to ISO 10993:2009, *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process.* A review of the testing has demonstrated that there are no new issues related to the safety or effectiveness of the Radiopaque Trial Necks. Clinical data was not needed to support the safety and effectiveness of the devices.

Substantial Equivalence Information

The Radiopaque Trial Necks have the same indications for use as the Smith & Nephew SMF Hip Stem System and MDF Revision Hip System. The material and sterilization of the subject devices is substantially equivalent to the Trial Inserts included in the Smith & Nephew Promos Reverse Shoulder System cleared by K081016. The design features of the Radiopaque Trial Necks have been compared to the previously cleared devices in Table 2 below.

Table 2: Comparison to Predicate Devices

Feature	Subject Radiopaque Trial Necks – K113039	Predicate SMF Hip Stem System - K080625	Predicate MDF Revision Hip Stem System - K081124	Promos Reverse Shoulder System Trial Inserts – K081016
Same Indications for Use	Yes	Yes	Yes	No
Implant/Instrument	Hip Trial Instruments	Hip Implants	Hip Implants	Shoulder Trial Instruments
Material	Polyphenylsufone (PPSUI) with 6% Barium Sulfate (Color Added)	Ti-6Al-4V – Stem Cobalt Chrome – Modular Necks	Ti-6Al-4V – Stem and Modular Sleeves Cobalt Chrome – Modular Necks	Polyphenylsufone (Color added)
Sterilization	Non-sterile	Gamma Sterilization	Gamma Sterilization	Non-sterile
Single Use or Reusable	Reusable	Single Use	Single Use	Reusable

Conclusion

This Traditional 510(k) premarket notification is being submitted to request clearance for the Smith & Nephew Radiopaque Trial Necks. Based on the similarities to the predicate devices and acceptable biocompatibility testing, the subject devices are considered substantially equivalent to the devices currently marketed under premarket notifications K080625, K081124, and K081016.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 5 2012

Smith & Nephew, Incorporated
% Ms. Natalie P. Williams
Sr. Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K113039
Trade/Device Name: Radiopaque Trial Necks
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semiconstrained cemented or nonporous uncemented prosthesis;
Regulatory Class: Class II
Product Code: LPH, MEH
Dated: October 4, 2012
Received: October 5, 2012

Dear Ms. Williams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113039

Indications for Use

510(k) Number (if known):

Device Name: Smith & Nephew Radiopaque Trial Necks

Indications for Use:

Total hip components are indicated for uncemented use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113039